

apresentação gráfica do conteúdo textual (verificadas no estudo analítico) podem influenciar negativamente nas estratégias de leitura da bula, particularmente pelos participantes com pouca experiência de leitura com este tipo de documento. **CONCLUSÕES:** Com base nos resultados de ambos os estudos foram elaboradas diretrizes e espera-se que estas possam contribuir com a melhoria na qualidade da estrutura e apresentação gráfica do conteúdo textual da bula de medicamento no Brasil.

PIH13

THE IMPACT OF FAMILY PHYSICIAN PROGRAM ON HEALTH INDICATORS IN IRAN (2003–2007)

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OBJECTIVES: “Family Physician” program has been launched since 2005 as a fundamental health plan in Iran. In spite of valuable information gathered through vital horoscope, only a few studies have been done in order to evaluate the performance of this program. So this research has been carried out to assess the impact of this program on health indicators. **METHODS:** The research involved collecting data about 11 main health indicators extracted from the official annual report of the deputy for health from 2001 to 2006 and analyzing them through t-paired test in SPSS **RESULTS:** Statistical analysis shows that the changes in 6 main indicators during these years including infant mortality rate, (IMR), crude birth rate, under-5 mortality rate (U5MR), neonatal mortality rate (NMR), maternal mortality rate (MMR), and percentage of deliveries attended by unskilled persons were significant (p -value $< 0/05$) and all of the above indicators have decreased during these years. Although other 5 indicators such as crude death rate (CDR), general fertility rate, percentage of deliveries in hospitals, percentage of family planning coverage and still birth rate had an appropriate improvement during these years, their changes were not statistically significant (p -value $> 0/05$). **CONCLUSIONS:** Findings indicates that there is an acceptable improvement in many of the health indicators since starting this program. But this does not mean that the other factors that might have affect on these indicators should not be considered.

INFECTION – Clinical Outcomes Studies

PINI

GENDER DIFFERENCES IN METABOLIC PROFILE AND CARDIOVASCULAR RISK AMONG BRAZILIAN HIV-INFECTED PATIENTS ON HAART: RAPID II STUDY

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OBJECTIVES: Gender differences in cardiovascular risk (CVR) among HIV-infected patients have been reported, with conflicting results. We have previously reported data from the Registry and Prospective Analysis of Patients Infected with HIV and Dyslipidemia (RAPID II study) a higher CVR in males and higher rates of obesity, metabolic syndrome (MS), and lack of physical exercise in females. We now compare gender differences among Brazilian individuals **METHODS:** Adult HIV-infected patients with at least 6 months of HAART were enrolled in this longitudinal study that is being conducted in 7 countries. Metabolic profile, anthropometric parameters, CD4-cell count, viral load (VL), types of HAART, CVR factors, and Framingham score were compared by gender **RESULTS:** A total of 1001 Brazilian patients were enrolled, 655 (65.4%) were males. Mean (SD) age was 44 (10) years, mean time on HAART was 48.4(36.4) months, 48% were on a protease inhibitors-based HAART, mean CD4-cell count was 519 (274) cells/mm³, and mean VL was 2.29 (0.9) log₁₀ copies/ml. Males were found to have higher 10-year CVR (15.9 ± 30.1 vs 11.0 ± 29.6 ; $P = 0.0136$) and were more likely to belong to the high-risk category (15.9% vs 10.4% ; $P = 0.021$) than females. No gender differences were found in the rates of hypertension, type II diabetes, or MS. Female patients showed higher prevalence of obesity (12.7% vs 7.2% ; $P = 0.005$) and physical inactivity (66.5% vs 53.6% ; $P < 0.001$) than males. In contrast, male patients were older (44.5 ± 9.4 vs 43.0 ± 10.4 years; $P = 0.0194$), and had higher rates of smoking (24.4% vs 17.6% ; $P = 0.016$) and dyslipidemia (81.8% vs 74.6% ; $P = 0.009$) than females **CONCLUSIONS:** Brazilian individuals sheds light on gender differences whose recognition may be important for appropriate intervention on modifiable CVR factors.

PIN2

INTEGRATION OF PHARMACO-ECONOMIC OUTCOME BASED RESEARCH WITH LOCAL CONTEXT: A MODEL FOR RATIONAL HEALTH CARE DECISION-MAKING IN DEVELOPING COUNTRIES

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BACKGROUND: Extrapolation of research data from developed countries, without considering the local context can sometimes result in outcomes different from the research setting, emphasizing the need to integrate external research with local context. An example of hepatitis B vaccination in India is presented as a model. **OBJECTIVES:** To decide whether hepatitis B vaccination should be introduced in India, by integrating pharmaco-economic research data with the local context. **METHODS:** Detailed

literature search was undertaken to identify evidence for: 1) hepatitis B disease burden in India; 2) efficacy and safety of Hepatitis B vaccination; 3) economic implications; 4) feasibility of universal administration; 5) local situation; and 6) expected short and long term outcome. Evidence was sought in the following hierarchy: systematic reviews, randomized trials and case control/cohort studies. **RESULTS:** A current systematic review¹ identified Hepatitis B prevalence as 1.7%; another (Cochrane) review² reported relative risk of hepatitis B following vaccination as 0.12(0.03–0.44) in per-protocol analysis, suggesting that prevalence could be decreased by 88% through universal vaccination. The cost of vaccine would be approximately 0.15US\$ per dose and vaccination cost per child approximately 0.60US\$ (1.8US\$ for three doses) if added to DPT vaccination administered to infants at 6,10,14 weeks of age; thereby making the intervention highly cost-effective in terms of reduction in disease prevalence (short-term outcome) and hepatitis B morbidity/mortality (long-term outcome). However current national data³ shows that DPT vaccine coverage is only 55.3%; further over one-third of hepatitis B infection is acquired perinatally⁴ and cannot be prevented through this vaccination schedule. Therefore, integrating local context with research data suggests that the expected 88% reduction in prevalence (from research data) would practically translate to only 37% reduction, whereby hepatitis B vaccination may no longer be cost-effective to reduce disease burden. **CONCLUSIONS:** It is critical to incorporate local contextual issues when pharmaco-economic outcome data is extrapolated from external research, especially in developing countries.

PIN3

HEPATOCELLULAR CARCINOMA (HCC) RISK ESTIMATION BASED ON CHRONIC HEPATITIS B (CHB) VIRAL LOAD LEVELS IN BRAZILIAN PATIENTS

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OBJECTIVES: The objective of this analysis was to apply a risk estimation model (REVEAL study by Chen, 2007) to predict HCC development in Brazilian CHB-infected subjects and to estimate the level of risk according to Viral Load distribution. **METHODS:** We evaluated: gender, age, family history of HCC, prevalence of alcohol consumption, ALT, HBeAg and HBV DNA levels. Patients were from different regions of Brazil, diagnosed with CHB at the DASA in 2007. Regression coefficients derived from the Cox models of Chen's study were converted into risk scores (RS) and the predicted risks of HCC over 5 and 10 years calculated by predicted 5/10 years HCC risk = $1 - (1 - P_0)^{\exp(RS - RS_0)}$; being: P₀: Predicted probability of HCC within 5/10 years for persons with the reference-level risk score RS₀ and RS: Risk score of which HCC risk to be predicted. Costs for treatment was reported by Castelo (2007). **RESULTS:** Of the total population (564) 64.5% were males and 62.1% were HBeAg negative. The median HBV DNA level was 1,789 and 72,924 copies/mL for HBeAg negative and positive patients, respectively. Patients male, older with high HBV DNA levels had the greatest risk of developing HCC. The mean (SD) estimated risk for 5 and 10 years in 1000 patients are 7.87 (6.82) and 18.30 (15.77), respectively. In patients older than 40 years old this risk is 27.34 (13.82) and for patients with HBV DNA levels higher than 10,000, the risk is 26.54 (15.75). The costs for treating these patients can vary from US\$34,861.50 to US\$50,558.70, if these patients are transplanted these costs can be from US\$639,548.40 to US\$927,519.92. **CONCLUSIONS:** This study suggests that the risk of HCC in the Brazilian HBV population is considerable and may significantly impact the health care system.

INFECTION – Cost Studies

PIN4

IMPACT OF CHRONIC HEPATITIS B IN THE BRAZILIAN HEALTH SYSTEM ACCORDING WITH DATA FROM DATASUS (ADMINISTRATIVE DATABASE) FROM MINISTRY OF HEALTH

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OBJECTIVES: The distribution of Chronic hepatitis B virus (HBV) in various Brazilian regions is not well understood. The public health and economic impact of Hepatitis B and its complications such as cirrhosis, and liver cancer in the Brazilian Unified Health System (SUS) will give further insights of the importance of the disease in Brazil. DATASUS is a public administrative database maintained by MoH and can contribute to the study of HBV. **METHODS:** HBV and its complications in the Brazilian SUS was evaluated in the public database DATASUS between 2000 to 2007. Data were tabulated according with different Brazilian states. **RESULTS:** Mortality data indicate a peak of viral hepatitis and liver cirrhosis between 40 to 60 years old, followed by another mortality peak due to liver cancer between 60 to 80 years old, this pattern is found in the states studied. The average hospitalization time for liver-related

disease is 9.16 days as compared with 5.83 days to all-causes hospitalizations. In some states, such as Minas Gerais and Federal District (Brasilia), a greater rate of Hospitalization authorizations (AIH) for liver-related diseases was observed compared to the rate for all-causes hospitalization. Lamivudine is the treatment of choice compared with interferon and others therapies, particularly after 2003 when lamivudine was included in the high cost list and made available for SUS. The costs for SUS is steadily increasing with liver transplant and immunosuppressive drugs in several states. For example, SUS expend R\$4,560,00 with transplants and more than R\$100,000,000 with immunosuppression in 2006. **CONCLUSIONS:** HBV and its complications exert a significant clinical and economic impact to the Brazilian Public Health System and suggest that existing therapies are inadequate to address the issue.

PIN5

CARGA FINANCIERA POR HEPATITIS A EN MÉXICO

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OBJETIVOS: La hepatitis A es una de las enfermedades virales más comunes que constituye un problema de salud pública en México. Se ha demostrado que la incidencia de la infección se ha estado desplazando a edades mayores, donde las consecuencias clínicas son más severas y más costosas. El objetivo de este estudio es determinar los costos de tratamiento de Hepatitis A y sus complicaciones, así como la carga financiera que ocasiona este padecimiento en México. **METODOLOGÍAS:** Se realizó un estudio en el que se llevó a cabo la revisión retrospectiva de expedientes clínicos de pacientes con diagnóstico de hepatitis A atendidos en cinco clínicas de segundo y tercer nivel del sector público de México. Par la recolección de la información, se desarrolló un instrumento que permitió recolectar los costos unitarios y utilización de recursos médicos utilizados en la atención de pacientes con hepatitis A y sus complicaciones, hepatitis colestásica, hepatitis fulminante. Para determinar la carga financiera anual se combinaron los costos estimados por caso con la incidencia anual correspondiente. **RESULTADOS:** El costo total anual estimado de hepatitis A y sus complicaciones fue de \$75,972,381 pesos (\$8,830,003–\$237,005,243). El costo por caso de hepatitis A ligera fue de \$1,186 (\$192–\$4,183) pesos, de \$5,942 (\$365–\$25,125) para hepatitis A grave, de \$9,967 (\$1,193–\$18,740) en colestásica y \$55,798 (\$14,462–\$97,134) en fulminante. **CONCLUSIONES:** Los resultados sugieren una alta carga financiera ocasionada por el aumento en la severidad de los casos, la determinación de los costos por caso será útil para conocer el impacto económico de la introducción de medidas preventivas como es la vacunación.

PIN6

COSTS OF NOSOCOMIAL PNEUMONIA IN A THIRD LEVEL HOSPITAL OF MEXICAN SOCIAL SECURITY INSTITUTE (IMSS)

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OBJECTIVES: To estimate direct medical costs of management of nosocomial pneumonia (NP) and ventilator-associated nosocomial pneumonia (VAP) in General Hospital (GH) of Raza National Medical Center **METHODS:** Data from nosocomial pneumonia patients who diagnosed according to Mexican Official Standard Nom-026-SSA2-1998 and received medical assistance in GH between 2006–08 were include in the study. The clinical response was used to assess clinical status (fail or successful in the first treatment). Costs were estimated from the hospital perspective using a bottom-up approach, and only direct medical costs were estimated (hospitalization, treatment, laboratory tests, specialist visit). Clinical data and resource utilization were obtained from individual clinical. The unitary costs used are those officially published by IMSS. A 5% discount rate was used, and costs were adjusted as to 2008. Results are shown as mean standard (SD) and pesos mexicans. Generalized Linear Model analysis was applied. Sensitivity analyses included variation of the main variables **RESULTS:** 113 patients were included, 70 with NP and 43 patients with VAP. Male 62%, age 57 ± 18 years, patients with NP and VAP due to *Pseudomonas aeruginosa* were 34%. Mortality were 24%. Patients with VAP who fail first treatment were 68% vs NP 53% (p = 0.03). More resources were utilized for VAP patients compared to NP in length of stay in days in intensive care unit 8.64 vs 3.7 days respectively (p < 0.0001). Average VAP costs per fail patient in first treatment were higher than successful patients MXN\$279,619.6 vs \$190,908.7 (p < 0.0001). In NN happened same situation \$172,411.2 vs \$132,306.4 (p = 0.001). 93% and 96% of total costs were due to hospitalization in patients with NP and VAP, respectively **CONCLUSIONS:** Strategies should be looked for to obtain better results since the first scheme of treatment with this type of patients to avoid incremental cost of a fail patient.

PIN7

COSTO-BENEFICIO DEL USO DE TIGECICLINA VS. TRIPLE ESQUEMA ANTIMICROBIANO CEFOTAXIMA/AMIKACINA/METRONIDAZOL EN PACIENTES CON INFECCIONES INTRAABDOMINALES Y DE PIEL Y TEJIDOS BLANDOS EN MÉXICO

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OBJETIVOS: Evaluar los costos y beneficios asociados a dos esquemas antimicrobianos en la atención de infecciones intraabdominales y de piel y tejidos

blandos: tigeciclina vs. el triple esquema cefotaxima/metronidazol/amikacina. **METODOLOGÍAS:** Se realizó una búsqueda bibliográfica con tigeciclina a fin de conocer las medidas de respuesta al tratamiento, los esquemas y dosis administrados. Se determinaron los costos directos médicos desde el punto de vista del Sector Salud en México. Los precios unitarios de los medicamentos e insumos incluidos fueron obtenidos de la lista oficial de precios del sector salud. Para identificar el consumo de recursos médicos se integró un panel de expertos. Los costos unitarios fueron obtenidos de los listados oficiales de esas instituciones. **RESULTADOS:** En términos de costos totales por paciente, el tratamiento con tigeciclina tiene un costo total de \$73,708 y de \$91,830 para el 2° y 3° nivel de atención respectivamente, durante un período de estancia de 7 días, y de \$147,416 y de \$183,660 para el 2° y 3° nivel respectivamente, durante un período de estancia de 14 días. En el caso de estar sujetos a un triple esquema y considerando una estancia hospitalaria mínima de 14 días, los costos totales con el triple esquema serían de \$155,243 y de \$209,299 para el 2° y 3° nivel de atención respectivamente. Bajo un escenario donde los pacientes pueden llegar a permanecer 6 semanas hospitalizados en casos muy severos, se tiene un costo total de \$465,730 y \$627,898 para el 2° y 3° nivel de atención respectivamente. **CONCLUSIONES:** Tigeciclina proporciona ahorros importantes a consecuencia de una disminución en las re-intervenciones quirúrgicas, ya que por tener un perfil de resistencia menor, la extensión y profundidad del proceso infeccioso se resuelve en menor tiempo.

PIN8

EVALUACIÓN DEL IMPACTO EPIDEMIOLÓGICO Y ECONÓMICO DE LA INTRODUCCIÓN DE LA VACUNA DE ROTAVIRUS EN EL PAÍS DE COLOMBIA

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OBJETIVOS: Estimar la carga de enfermedad diarreica aguda (EDA) y enfermedad atribuible a rotavirus en menores de dos años, y modelar el impacto epidemiológico y económico de la introducción de la vacuna de rotavirus en Colombia. **METODOLOGÍAS:** 1. Revisión sistemática y análisis descriptivo de la literatura nacional e internacional y de fuentes de información no publicadas y 2. Estudio de evaluación económica del impacto de la introducción de la vacuna. **RESULTADOS:** Se estima que en el 2007 en Colombia ocurrieron aproximadamente: 2,737,794 (IC95% 2,421,178–2,979,911) casos de diarrea en menores de 2 años, de los cuales 98,049 (IC95% 86,710–106,719) requirieron hospitalización. Se estimaron 328,535 casos ocasionados por el rotavirus, 108,417 (IC95% 78,446–132,308) consultas ambulatorias atribuibles al rotavirus, 37,258 (IC95% 26,013–45,889) hospitalizaciones y entre 295 y 560 muertes por diarrea debida a rotavirus. Los costos de la carga de enfermedad por EDA en Colombia, en ausencia de un programa de vacunación contra rotavirus, equivalen a US\$30.9 millones (US\$27.3–US\$33.6 de 2007) que cubren gastos de atención médica y costos indirectos representados por la pérdida de productividad de padres o acompañantes. Los costos anuales evitados por el programa de vacunación podrían estar entre US\$5.7 y US\$8.1 millones, es decir, una disminución del 18.5% al 26% de los costos totales ocasionados por la EDA en Colombia. La vacunación presenta una razón de costo efectividad incremental de US\$ 500 por año de vida salvado y US\$34,985 por muerte evitada. **CONCLUSIONES:** En Colombia, la vacuna contra el rotavirus es muy costo efectiva, ya que la relación costo efectividad calculada es menor que el valor del PIB per cápita, evaluado en US\$3229 para el 2007. Se recomienda considerar la introducción de esta vacuna en el territorio nacional.

PIN9

MODELO FARMACOECONÓMICO VORICONAZOL EN ASPERGILOSIS INVASIVA: CASO VENEZUELA

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OBJETIVOS: La alta mortalidad asociada al aumento de la enfermedad invasiva fúngica hace que sea muy importante la evaluación del costo-efectividad de las diversas estrategias en tratamiento de estas patologías sobre todo teniendo en consideración la toxicidad de los esquemas tradicionales. **METODOLOGÍAS:** Se realizó un modelo de costo efectividad basado en la metodología de análisis de decisión comparando dos estrategias de tratamiento en aspergilosis invasiva a saber : Anfotericina B Deoxicolato frente a Voriconazol. Para ello se asumieron : 1) Las probabilidades de efectividad terapéuticas fueron basadas en estudios de referencia publicados 2) Los costos directos de tratamiento fueron basado en tratamiento de enfermedad fúngica invasiva en entorno de hospital privado 3) Modelo matemático realizado en Excel 2003 con las siguientes características : Horizonte temporal de 12 semanas (ambulatorio + hospitalizado) 4) Probabilidad de valor fijo 5) Perspectiva de pagador 6) solo costos directos, los pacientes en falla clínica se manejan con esquemas de antifúngicos varios. Se calculó el costo total por estrategia, costo promedio por paciente, costo de caso exitoso, costo de caso con falla primaria y costo porcentual imputable a antifúngicos dentro del esquema. Se realizó análisis de sensibilidad basado en variabilidad 10%. **RESULTADOS:** El costo promedio de paciente tratado con Anfotericina B Deoxicolato fue de US\$23,827 frente a Voriconazol US\$19,361, el costo por sobreviviente en Anfotericina B deoxicolato fue de US\$65,453 frente a US\$36,695. **CONCLUSIONES:** La estrategia predominante en base al costo-efectividad sería Voriconazol para tratamiento de aspergilosis.